

OptTEST Evaluation Methodology & Plan

1. Introduction

The purpose of this evaluation plan is to guide the monitoring and evaluation of the process, output and outcome of optTEST. The evaluation of the OptTEST project is described in Work Package 3 (WP3), which is the horizontal work package responsible for the monitoring of actions undertaken to verify that the project is being implemented according to plan and that it reaches the set objectives. Evaluation of the core work packages (4-7) is described in more detail in section 4.

Milestones WP3:

1. **Evaluation methodology and evaluation plan (M6, December 2014).**
2. **Progress report year 1 (M12, May 2015)**
3. **Mid-term external evaluation (M18, November 2015)**
4. **Progress report year 2 (M24, May 2016)**
5. **Final report (M36, May 2017)**

The evaluation plan for OptTEST builds on four basic tools of evaluation, which will feed into the yearly progress reports, the external mid-term evaluation and the final report:

- 1) Baseline data
- 2) Process evaluation
- 3) Output evaluation
- 4) Outcome evaluation

For all phases of the evaluation it is important that the set indicators are SMART (specific, measurable, achievable, realistic and timely).

The Evaluation's four steps

Step 1: Baseline data

Baseline data will be collected for work packages 4, 5 and 7; this will allow ongoing comparison to determine if the planned project actions have their desired effect.

In order for the evaluation to be as effective as possible, it is important that it is planned before the implementation of the project or within the first six months. This way, it is possible to identify the appropriate indicators and possible comparison groups/countries/settings, to determine a baseline for the key outcome indicators.

Baseline data may be collected from the countries where the project is present (pilot countries) as well as other comparable countries, which can be used as quasi-experimental comparisons when evaluating the project's specific impact.

Step 2: Process evaluation

The *process evaluation* focuses on assessing or measuring the activities in the project and their quality. It is a reflection on the project's achievement of the objectives so far – what is going well and what should be altered or improved. The process evaluation should feed into the **progress report year 1 and 2** and the **external mid-term evaluation** and thus functions as a useful tool to improve the on-going project implementation.

The *process evaluation* needs to be closely linked to the project's stakeholder analysis and communication strategy documents. Throughout the project implementation period, it is key to take into account the views and involvement of the project's target groups (health care professionals and (non) HIV clinicians, health care managers, social workers, researchers, civil society organisations, policy makers and government officials, & the press).

Some of the central process-related questions to ask are:

Overall: Are the right things being done in the right way?

- Are all the activities of the project being implemented?
- Have milestones been met on schedule?
- What is holding up progress?
- What should be done to correct this?
- Is project management effective? Are there adequate project management systems in place?
- Are all major partners and stakeholders on board? Do they agree with interim findings?
- Is the project well oriented to (and reaching) the target group? Are target groups satisfied with the project?
- Are all the elements and components of the project of good quality?

Step 3: Output evaluation

The *output evaluation* is about demonstrating whether the project has achieved its aims and objectives, whether it is useful and of benefit to the target groups (OptTEST Stakeholder Analysis and Communications Strategy 2014). Focus is on assessing or measuring immediate impact and effects of the project for the main target groups and stakeholders.

This part of the evaluation should feed into the **final report**.

Some of the central output related questions to ask are:

Overall: Is the project making a difference? Are things being done on a large enough scale?

- Have project objectives been met?
- What are the key findings?
- Is the dissemination effective?
- What impact has the project had? (E.g. what is the increase of offered HIV tests for patients presenting with an indicator disease? (WP5).

- What benefits are there for target groups and stakeholders?
- Is the approach effective?
- What lessons have we learned so far?
- What would we do differently?

Step 4: Outcome evaluation

The final step in the evaluation plan is the *outcome evaluation*, which is related to assessing or measuring if the project has had any effect on the target group over the three-year project period. Part of assessing project outcomes is through performance indicators that may relate to user demand, user satisfaction, efficiency, effectiveness, up-take, etc.

This is generally associated with the overall goals of the project and generally outcomes need to be measured over a twelve month period or longer. Naturally, some of the outcomes will only be fully measurable after the project has finalized.

This part of the evaluation will feed into the **final report**.

Some of the central questions to ask are:

Overall: Have the right people been reached?

- Have project outcomes been achieved (improvements in earlier diagnosis, retention in care, no. of late presenters etc.)?
- Are knowledge and results being shared with the wider community?

2. Evaluation Methods

The following methods will be used in the ongoing evaluation of the project.

Quantitative methods:

- Questionnaires
- Usage logs
- Web server logs

Qualitative methods:

- Interviews
- Focus groups
- Observations

3. Evaluation of the Communication Plan

During the external mid-term evaluation, it will also be appropriate to assess the effectiveness of the communication strategy with both our internal (advisory board, HiE steering committee) and external audiences. For example looking at:

Evaluation Plan V12 16JAN2015

- Reporting on outputs and results of implementation
- Registration of press mentions
- Web statistics
- Interest groups analysis (before and after implementation)
- Publication in scientific medical and public health journals

The stakeholder analysis/communication strategy may be adjusted according to the results of the mid-term evaluation.

4. Evaluation per Work Package and Specific Objectives

In the following, the **evaluation plan will be specified for work packages 2,4,5,6 and the project's five specific objectives.**

Each work package should contribute to the project evaluation by **collecting relevant baseline data** from the very start of the project. This will help the overall monitoring process of whether the planned project actions are implemented effectively and have had the desired effects.

Below are tables for work packages 2,4,5,6, and 7 and specific objectives, listing process, output and outcome indicators from the project description.

Indicators in **bold** are what the project committed to in the Technical Annex (Annex Ia) in the project proposal.

Work Package 2 (+ others) : Dissemination of the project			
Specific Objective 1:	<i>To improve multi-profession, multi-country stakeholder dialogue to develop strategies to improve early diagnosis and care of people with HIV across Europe by 2016</i>		
Milestones	Milestone 1: Communication and dissemination strategy Stakeholder analysis Milestone 2: OptTEST website (Update regularly) Milestone 3/deliverable: Promotional leaflet (English, French, Spanish and Russian) Milestone 4: Press releases/position statements year 1, 2, 3 Milestone 5: Public final project report (English, French, Spanish and Russian)	M6 M6 M6 M12, M24, M36 M36	
Baseline data	Process Indicators	Output Indicators	Outcome Indicators
Baseline data is only collected for the core work packages (4-7)	'Inclusive' – broad spectrum of stakeholders (professional background, institution, country); 'collaborative' – all views	Creation of Project Website 4 annual newsletters At least 1 500 users per year	>500 stakeholders participated in discussing project outcomes By M36

	heard/respected; 'competent' – participants treated as experts in their field	will visit the website M12, M24 & M36 Website monitoring: Usage of the portal will increase by 200% from year 2 to year 3	
	Feedback of project activities through different stakeholder networks and meetings M12, M24, M36	Obtain >75% attendance of invitees in each scheduled project meeting M12, M24 & M36 Minutes of meetings in all WPs by M12, M24, M36	Stakeholder meeting by Y3 with broad European participation. OptTEST is referred to/invited to present at events of stakeholders/ in their newsletters, link on websites, etc. (Think Tank, Civil Society Forum, 3 events at National level)
	At least one annual project-related presentation at an international HIV conference M12, M24 & M36	At least one project-related publication in a peer reviewed international scientific journal, distributed to >500 stakeholders M12, M24 & M36	The formulation, publication and dissemination of agreed upon regional guidelines to improve early diagnosis and care of people with HIV across Europe by M36
		Geographical coverage, priority groups reached, equal distribution of type of stakeholders, participation documented by M12, M24 & M36	Survey analysing implementation of tools and guidance by M36 <ul style="list-style-type: none"> 90% of users questioned will find the guidelines and tools are useful

Work Package 4: Linkage to and retention in HIV care after diagnosis		
Specific objective 2:	<i>To increase knowledge on linkage to and retention in HIV care after diagnosis across geographical and healthcare settings and target groups by 2016</i>	
Milestones	<p>Milestone 1: Literature review of current evidence and definitions used to measure link to and retention in HIV care and patient experience, as well as experienced barriers</p> <p>Milestone 2: Agreed surveillance definitions</p> <p>Milestone 3: Collation of service data from 7 European countries</p> <p>Milestone 4: Report of treatment cascade evidence across 7 European countries</p> <p>Milestone 5: Best practice guidelines</p>	<p>M6</p> <p>M9</p> <p>M18</p> <p>M34</p> <p>M34</p>

Baseline data	Process Indicators	Output Indicators	Outcome Indicators
Identification and outline of practices and differences in linkage to care and retention in care by site and region	Literature review finalized by M12	Existing data on diagnosis and linkage to care in the EU/EEA made available by M12	Dissemination of literature review outlining current practices and continuum of care models in Europe to stakeholders
	Country survey on HIV testing, national policy and guidelines and data availability	Audits (1): 7 Countries that are able to collect data on people with an HIV diagnosis linked to care by M24	Consensus on standard definition of linkage to care and appropriate tools i.e. comparable “treatment continuum” to assess the level of linkage to and retention in care by M18
	Consultation with key stakeholders by M14	Meeting report with proposed definitions	
	Assess effectiveness of existing systems in place to monitor linkage to and retention in care using proposed definitions by M12	All pilot countries to have provided data to PHE Creation of continuum of care for pilot countries by M24	Dissemination of results of audits: 1 abstract/ 1 conference presentation of the results of the audits. By M24 – M28
Identification of stigma and legal/ criminalisation barriers to linkage to care	Literature review finalised by M12 in collaboration with WP 7	Report on legal and regulatory barriers to linkage to care by M12 (WP7)	Dissemination to stakeholders (WP7)
	Analysis of data from pilot and collaboration with stakeholders to develop best practice guidance	Production of expert-agreed recommendations and implementation tools; furthermore, a standardised assessment tool to assess/audit linkage to care at a country/ regional level by M34	Dissemination of pertinent information to wider audiences (1 publication in Journals/ 2 presentations at conferences) at M12, 24 & 36.
	Pilot implementation tools for measuring linkage to and retention in care in 7 countries by M18: IWHOD cohort workshop, March 2015 (Sicily): Create consensus on indicators for linkage to care.	Audit (2): people with an HIV diagnosis linked to care, after implementation of standard definition and appropriate tools. In countries that are able to monitor people with an HIV diagnosis. By M28	Reassessment of sites after implementation – An increase in the number of countries who are able to monitor HIV positive people linked to treatment and care by M30-6

Work Package 5: Development and implementation of tools and strategies for indicator condition guided testing.		
Specific objective 3:	Create understanding and suggest evidence-based solutions to provider barriers to testing through pilot implementation of a novel HIV testing strategy (Indicator Condition-guided) in selected European healthcare settings and countries by 2016	
Milestones	Milestone 1: Mapping of current national/regional HIV testing guidelines, best practices and data requirements; stigma and legal barriers (taking account of information governance and ethical requirements)	M12
	Milestone 2: Implementation of tools (at least 1 tool in each country for each of the three IC)	M18
	Milestone 3: Training modules with competency assessments and certifications available on-line –this is tool 3, so milestones 2 and 3 are not mutually exclusive	M30
	Milestone 4: Results to contribute to the finalising of good practice manual on legal barriers	M34
	Milestone 5: Publication of findings in peer-reviewed journals	M34

Baseline Data	Process Indicators	Output Indicators	Outcome Indicators
<p>Identification of current National HIV testing guidelines, specialty and regional guidelines.</p> <p>Identify barriers at national, specialty and organisational level</p>	<p>Scoping and mapping – baseline data collection forms (Part 1) completed by partners and pilot sites – M12</p>	<p>Report on guidelines lacking IC recommendation, evidence of stakeholder involvement in guidelines</p>	<p>Changes to any guidelines, recommendations, policies</p>
<p>Local guidelines and policies</p>	<p>Baseline data collection forms (Part 2) completed by pilot sites – M12</p> <p>Use of at least 1 of the tools by each active site - M36</p>	<p>Examples include: Use of Tool 1 e.g. relevant presentation at Hospital teaching round, HIV testing as an agenda item at health service Board/committee meeting,</p> <p>Development of implementation tools – 1 per IC for each country - M18</p> <p>TOOLS – on website M36 (+CHIP action)</p>	<p>Production of local guidance and policies</p> <p>Initiation of HIV testing programme in IC</p> <p>Production of local guidance/event relevant to each tool</p>

Baseline Data	Process Indicators	Output Indicators	Outcome Indicators
Identify HCP education and training requirements, including any individual level barriers to offering HIV test	HCP completion of staff questionnaire HCP use of tool 3 by at least 2HCP (or 50% of staff) in active IC clinic	Report on training needs and barriers identified via HCP staff questionnaire; at least 1 pilot site in each of 7 countries – M18 Number of successful HCP certifications	Overall improvement in knowledge and reduction in perceived barriers Improved testing behaviour
HIV testing levels for each IC at each pilot site and country	Completion of relevant part of baseline data form (Part 2) HIDES II audit inclusion One pilot site in each of the 7 countries ready to deliver testing for one IC - M24 Redcap data on HIV testing - Denominator HIV test offered HIV test accepted HIV test result CD4 cell count	50% increase in proportion of IC patients testing for HIV by M36 If baseline levels of testing >50%, then a 15% increase is required Web-based – regional and IC adapted - implementation tool available. By M36	New HIV diagnoses in pilot site IC service Median CD4 count is higher than local/national average
HIV testing levels for each IC at each pilot site and country	Development of an agreed upon ‘quality improvement methodology’ by M12-18 Development of PDSA cycles	Data demonstrating increasing levels of testing in response to QI (e.g. PDSA cycle (Plan-Do-Study-Act), SPC (statistical process control))	Increased HIV testing
			Dissemination of findings to relevant stakeholders. Reports to pilot sites. Publication in peer reviewed journal or presentation of findings at conferences (national IC specialty or international) at M24 & M36

Work Package 6: The cost effectiveness of HIV testing strategies in priority groups and regions		
Specific objective 4	<i>To assemble and evaluate various existing HIV testing strategies in Europe by 2016</i>	
Milestones	Milestone 1: To assess country-specific information regarding HIV testing policies and practices in different European countries France, Spain, and Estonia. And also performance of testing strategies to be evaluated (% of HIV	M6

	<p>positive; % linked to care; CD4 at HIV testing/HIV care.</p> <p>Milestone 2: To estimate the overall prevalence and incidence of HIV, incidence of HIV, and CD4 count at initiation of care in different European countries. & To estimate direct costs of routine HIV medical care in different European countries</p> <p>Milestone 3: To estimate survival benefits, costs, and cost-effectiveness of different HIV screening strategies in different European countries</p> <p>Milestone 4: Data made available on survival benefits, cost and cost-effectiveness</p> <p>Milestone 5: Publication in peer-reviewed journal</p>		<p>M18</p> <p>M24</p> <p>M28</p> <p>M36</p>
Baseline data	Process Indicators	Output Indicators	Outcome Indicators
Identification of European HIV testing strategies by region/country (M6)	To assess country-specific information regarding HIV testing policies and practices in different European countries France, Spain, and Estonia And also performance of testing strategies to be evaluated (% of HIV positive; % linked to care; CD4 at HIV testing/HIV care) & related cost by M18	Production of Data on survival benefits, cost and cost-effectiveness of different strategies by M24	Data available on survival benefits, cost and cost-effectiveness by M28
Workshops with a European Scientific committee to validate strategies to be evaluated (Modellers, ECDC, Decision makers and scientists from each country: Once a year	20 participants at 3 dissemination workshops (to actually validate input data for the model)	20 participants at 3 dissemination workshops (to actually validate results of the analysis)	
	Communication summaries disseminated to >250 relevant stakeholders at M12, M24 & 36	Dissemination of pertinent information to wider audiences (annual publications in Journals/ presentations of findings at international HIV conferences) in M12, M24 & M36	

Work Package 7: Stigma and legal/regulatory barriers to the provision and uptake of HIV testing services	
Specific objective 5:	<i>To increase knowledge of how stigma and legal/regulatory barriers affect the uptake of HIV testing and treatment, particularly in most affected groups and regions by 2016</i>

<p>Milestones</p>	<p>Milestone 1: Compilation of data from PLHIV stigma Index Countries in the region</p> <p>Milestone 2: Methodology to identify and document strategies to address stigma , legal and regulatory barriers developed and approved ; New advocacy resources section on OptTEST Website</p> <p>Milestone 3: Case studies and completed interviews with stakeholders on innovative strategies (10 legal and regulatory , 15 stigma index related)</p> <p>Milestone 4: Final report on lessons learnt on strengthening advocacy methodology to identify and document strategies to address legal and regulatory barriers developed and approved</p> <p>Milestone 5: Stigma and legal/regulatory barriers best practice manual available on OptTest Website</p>	<p>M6</p> <p>M12</p> <p>M24</p> <p>M24</p> <p>M34</p>	
Baseline data	Process Indicator	Output Indicators	Outcome Indicators
<p>A full review of existing information on stigma & legal barriers in the region</p>	<p>Measure/identify Country/Regional barriers to testing and linkage to care by M10</p>	<p>25 case studies to identify barriers to access to testing and linkage to care (identified in collaboration through WP 4 and 5) M24 This is a consolidation of Legal barriers and Stigma barriers</p> <p>Interviews with key stakeholders informing these case studies also completed where appropriate (M10) – 25 in total</p>	<p>Compilation of existing stigma index data and methodology by M12</p> <p>Production and dissemination of approved best practice guidelines to mitigate context-specific stigma & legal barriers by M36.</p>
	<p>5 different country strategies to counter stigma to testing/treatment developed and agreed upon by M12</p>	<p>>50 stakeholders' comments regarding stigma and legal barriers incorporated in draft manual by M12</p>	<p>Focus-group interviews (with the 5 PLHIV networks): to gauge effectiveness of the new context-transferable stigma index in aiding advocacy efforts to reduce barriers to testing and treatment; periodically from M24-34</p>
	<p>Documented and agreed upon identification and classification of barriers to linkage i.e. stigma/ criminalisation / lack of</p>	<p>The development and validation of a context-transferable stigma index to measure the impact of stigma on access to testing</p>	<p>Integration/utilisation of new stigma index within the 'treatment cascade' notion (SO2:WP4)</p>

	appropriate infrastructure/ resources/ policy, etc.) by M18-20	and linkage to care by M20	
		Development of transferable guidelines as to mitigate (stigma) barriers to testing and care	75 HCP demonstrating appropriate knowledge of how to mitigate known barriers (stigma) to testing and care